REMARKS

Claim Rejections – 35 USC §112, first paragraph

In the Office Action dated July 28, 2003, the Examiner rejected claims 24 and 59 – 64 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most merely connected, to make and/or use the invention. The Examiner explained that the disclosure is not seen to be sufficient to enable the use of any compound that comprises active agents A – F to normalize [treat] impaired or deteriorating neurological function without undue experimentation.

These rejections are respectfully traversed.

The Examiner cited *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Circ. 1988) in support of this contention. With respect to each of the factors mentioned by the Examiner, we note the following.

The breadth of the claims – The Nature of the invention

On page 4 of the Office Action, the Examiner stated that claims read on treating and curing any and all diseases relating to the nervous system and neurological disorders. The Examiner's statement is partly incorrect. Neither the claims nor the description of the invention mention a cure or curing. There is no one-to-one correlation between treatment and cure. See the Declaration of Edward Larry McCleary (hereinafter "McCleary Declaration), paragraphs 8 and 9. Applicant agrees, however, that the claims read on treating substantially all diseases relating to the nervous system and neurological disorders, as explained below.

An impaired or a deteriorating neurological function can be treated without necessarily curing it. See the McCleary Declaration, paragraphs 12 and 15.

An important teaching of the present application is that a relatively finite number of mechanisms, or pathways, are common to all impaired or deteriorating neurological functions. See the McCleary Declaration, paragraphs 10, 14 and 18. These common pathways are implicated, in varying degrees, in any neurologic insult or disease. See the McCleary Declaration, paragraphs 10 and 14.

Using the teachings of the Specification, his knowledge and skills, and a method in

accordance with claims 24 and 59 – 64, one skilled in the art is able to formulate a composition and administer it to a patient to treat suitably any impaired or deteriorating neurological function. See the McCleary Declaration, paragraphs 11 and 21. Also, see the Specification, page 17, lines 3 –5, 14 – 16, 29, and 30; page 27, lines 6 – 12; and page 29, lines 1 – 6.

A method in accordance with claim 24 treats an impaired or deteriorating neurological function through the administration to a patient for a therapeutically effective period an effective amount of a composition comprising a plurality of agents that in combination provide multiple simultaneous avenues of intervention in multiple disease mechanisms or pathways of any neurological disease. See the McCleary Declaration, paragraph 22.

Using compositions and methods in accordance with the invention, one skilled in the art more likely treats many or all of the abnormal mechanisms, or pathways, by which a particular disease process affects neurological function, rather than treating only one or a few of the mechanisms commonly recognized and associated in the prior art with the particular disease. See the McCleary Declaration, paragraphs 23 and 25.

The state of the prior art

The Examiner stated that the references enclosed showed that each of the functions are well known in the prior art, though a composition of the combination is not known.

One skilled in the prior art, for example, a physician, typically knows and recognizes one or several predominant mechanisms arising from a particular insulting stimulus of a particular disease process. See the McCleary Declaration, paragraph 16. For example, a neurosurgeon cares for a patient that might have a blood clot or a tumor in the brain; a neurologist might care for a patient with Alzheimer's disease or Lou Gehrig's disease; a neonatologist cares for a premature baby. See the McCleary Declaration, paragraph 16. Each of the specialists typically has a good idea of one or several predominant abnormal mechanisms associated with a particular disease or condition that underlies impaired or deteriorating neurological functions. See the McCleary Declaration, paragraph 16. Teachings of the prior art, however, typically lack a comprehensive overview including all of the common mechanisms implicated in all neurological diseases. See the McCleary

Declaration, paragraph 17. Therefore, a practitioner using the prior art lacks the knowledge and skills that would enable him to influence therapeutically more than one or a few of the various dysfunctional mechanisms. See the McCleary Declaration, paragraph 17.

The level of one of ordinary skill

The Examiner stated that the level of ordinary skill in the art is that of an MD and/or a Ph.D. skilled in the development of therapeutics for neurological disorders.

As argued above, a practitioner using the prior art typically lacks the knowledge and skills that would enable him to influence therapeutically more than one or a few of the various dysfunctional mechanisms. See the McCleary Declaration, paragraph 17.

It is clear that one skilled in the art will customize administration of a composition to a patient depending on various factors, including the disease treated, the particular agents used, the route of administration, and the condition and age of the patient. See the McCleary Declaration, paragraph 26. Nevertheless, only by applying a method in accordance with the invention is one skilled in the art able to select agents suitable for influencing therapeutically many or all of the common disease mechanisms identified in the Specification. See the McCleary Declaration, paragraph 26.

The level of predictability in the art

The level of predictability of therapeutic outcome in the prior art of the field of treating neurological dysfunction is low in the sense that, firstly, the efficacy of every treatment varies from patient to patient, and secondly, practitioners in the prior art typically limit their treatments to only one or several of the disease pathways of a particular disease condition, rather than treating numerous common pathways that cause impaired or deteriorating neurological function. See the McCleary Declaration, paragraph 24. As a result, the predictability of therapeutic outcome is hampered. See the McCleary Declaration, paragraph 24.

Using compositions and methods in accordance with the invention, one skilled in the art more likely treats many or all of the abnormal mechanisms, or pathways, by which a particular disease process affects neurological function, rather than treating only one or a few of the mechanisms commonly recognized and associated in the prior art with the

particular disease. See the McCleary Declaration, paragraph 25. This improves predictability of therapeutic outcome. See the McCleary Declaration, paragraph 25.

The amount of direction provided by the inventor

The Specification discusses many agents of various categories of agents suitable for influencing one or more disease mechanisms or pathways in certain ways. See the Specification, discussion of components A – M at pages 15 – 25. The Specification also teaches effective and preferred ranges of agents at pages 25 – 27, and methods of administering compositions at pages 27 and 28. Guided by teachings in the Specification (including the claims), one skilled in the art is able to customize administration of a composition to a patient depending on various factors, including the disease treated, the particular agents used, the route of administration, and the condition and age of the patient. See the McCleary Declaration, paragraphs 22, 26 and 27.

The breadth of claim 24 and a general teaching of the Specification is that a method in accordance with the invention is suitable for treating all impaired or deteriorating neurological functions. See the Specification, page 15, lines 19, 20, 23, and 24; page 16, lines 21 – 25; page 17, lines 3 – 5; page 27, lines 6 – 9; page 29, lines 1 – 6; and the McCleary Declaration, paragraphs 10 and 15. As argued previously, the Specification specifically discusses several disorders as examples of impaired or deteriorating neurological functions that can be treated in accordance with the invention. These examples were not intended to be limiting.

The existence of working examples

A preferred embodiment of an orally administered composition in accordance with the invention is disclosed in the Specification at page 25, line 16, to page 28, line 7.

Additionally, in view of the otherwise enabling disclosure of the Specification, Applicant argues that a working example is not required. MPEP 2164.02, referring to *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

The quantity of experimentation needed

If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 USC

112, first paragraph. MPEP 2164.01(c).

In view of the high level of skill in the field of neurological therapy, the discussion of components A – M at pages 15 – 25 of the Specification, the teaching of effective and preferred ranges of agents at pages 25 – 27, and methods of administering compositions at pages 27 and 28, one skilled in the art is able to practice the invention defined in claim 24 without significant experimentation. See the McCleary Declaration, paragraph 27.

Claim Rejections – 35 USC §112, second paragraph

Claims 1, 24, and 53 – 64 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

In accordance with comments of the Examiner, claims 1 and 24 have been amended to delete the word "normalizing" and replace it with "treating".

In accordance with comments of the Examiner, claims 56 and 62 have been amended to delete the word "hyperzine" and replace it with the term "huperzine A".

In accordance with comments of the Examiner, claims 59 – 64 have been amended to properly relate the dependent method claims 59 – 64 to the independent method claim 24.

For the above reasons, claims 1, 24, and 53 – 64 are believed to be patentable, and their reconsideration and allowance are respectfully requested. Also requested are reconsideration and allowance under 37 CFR 1.141 of previously withdrawn species claims 2 – 23, and 25 – 52. The undersigned attorney requests the Examiner to telephone the undersigned if a conversation could expedite prosecution. No additional fee is seen to be required, but if a fee is required, please charge it to Deposit Account No. 50-1848.

Respectfully submitted,
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